ATTACHMENT 2

NRC INSPECTION REPORT 030-01997/2002001 (DMNS)
ST. JOSEPH MERCY HOSPITAL

December 10, 2002

EA-02-248

Julie MacDonald
Senior Vice President & Chief Operating Officer
St. Joseph Mercy Health System
St. Joseph Mercy Hospital
5301 East Huron River Drive
Ann Arbor, MI 48106-0995

SUBJECT: NRC INSPECTION REPORT 030-01997/2002001(DNMS)
ST. JOSEPH MERCY HOSPITAL

Dear Ms. MacDonald:

This refers to the special inspection conducted from October 4 through 16, 2002, at St. Joseph Mercy Hospital, Ann Arbor, Michigan, with continued in-office review through November 15, 2002. The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions regarding your radiation safety officer's October 1, 2002, written report of exposures to several members of the public in excess of the NRC's annual limit of 100 millirem, and to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. The members of the public were family members of a radiopharmaceutical therapy patient who had been hospitalized for compliance with 10 CFR Part 35.75. Our inspectors determined from calculations that the patient's daughter, who was the maximally exposed member of the public, received an exposure of 15 rem total effective dose equivalent. The in-office review included a review of the results of the NRC medical consultant's evaluation of the exposure to the patient's daughter.

The enclosed copy of our inspection report identifies areas examined during the inspection. Within these areas, the inspection consisted of a selective examination of procedures and representative records, observations, independent measurements, and interviews with personnel and members of the public. On October 16, 2002, the preliminary inspection findings were discussed with you and members of your staff. The inspection findings and conclusions were discussed with you during a telephone conference call with Gary Shear and Darrel Wiedeman of my staff on November 21, 2002.

Based on the results of our inspection, we identified three apparent violations, which are being considered for escalated enforcement action in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600 (enclosed). These apparent violations include the failure to: (1) limit the dose to individual members of the public to 0.1 rem in a year; (2) use procedures and engineering controls, to the extent practical, based upon sound radiation protection principles, to achieve doses to members of the public that are as low as is reasonably achievable; and (3) investigate an overexposure to a member of the public and implement corrective actions. In addition, we identified three potential violations which are not being considered for escalated enforcement

action. These violations include the failure to: (1) include estimates of each individual's dose in your initial August 15, 2002, written report; (2) measure the dose rates in the contiguous unrestricted areas following the administration of a radiopharmaceutical therapy dosage requiring hospitalization; and (3) limit the dose in unrestricted areas to 2 millirem in any one hour.

The NRC contracted with a medical consultant to review the circumstances of this event, specifically with regard to the exposure to the daughter of the therapy patient. Our consultant determined that the exposure to the daughter may result in less than a one percent increase in the lifetime risk of cancer. Enclosed with this letter is a copy of the consultant's report for your review.

Since the NRC has not made a final determination in this matter, no Notice of Violation is being issued for these inspection findings at this time. In addition, please be advised that the number and characterization of apparent violations may change as a result of further NRC review.

A predecisional enforcement conference, open for public observation, to discuss these apparent violations has been scheduled for January 16, 2003, at 1:00 p.m. (CDT) in the Region III office in Lisle, Illinois. The decision to hold a predecisional enforcement conference does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference is being held to obtain information to assist the NRC in making an enforcement decision. This may include information to determine whether a violation occurred; information to determine the significance of a violation; information related to the identification of a violation; and information related to any corrective actions taken or planned. The conference will afford you an opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration in making an enforcement decision. In presenting your corrective action, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful.

You will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding these apparent violations is required at this time.

In accordance with 10 CFR Part 2.790 of the NRC's "Rules of Practice," a copy of this letter and Enclosure 1 will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room).

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

/RA/

Marc Dapas, Acting Director
Division of Nuclear Materials Safety

Docket No. 030-01997
License No. 21-00943-03

Enclosure 1: Inspection Report 030-01997/2002001(DNMS)
Enclosure 2: NUREG 1600
Enclosure 3: Excerpt from Information Notice 96-28
Enclosure 4: Medical Consultant's Report

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REGION III

Docket No.:	03001997
License No.:	21-00943-03
Report No.:	03001997/2002001(DNMS)
Licensee:	St. Joseph Mercy Health System Ann Arbor, MI 48106-0995
Locations:	St. Joseph Mercy Hospital 5301 East Huron River Drive Ann Arbor, MI
Dates:	October 4 - 16, 2002 w/continued in-office review through November 15, 2002
Exit Meeting:	October 16, 2002 (Preliminary) November 21, 2002 (Final Exit)
Inspector:	Jamnes L. Cameron, Team Leader Darrel Wiedeman, Senior Health Physicist
Approved By:	Gary L. Shear, Chief Materials Inspection Branch Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

St. Joseph Mercy Health System
Ann Arbor, Michigan
Inspection Report 03001997/2002001(DNMS)

This was a special inspection to review the circumstances, root and contributing causes, and proposed corrective actions associated with an event involving exposures to individual members of the public in excess of 0.1 rem (100 millirem) total effective dose equivalent. The overexposures resulted from close contact, over several days, with a hospitalized patient who had been administered 285 millicuries of sodium iodide iodine-131. The licensee's report indicated that the event may have involved as many as 20 individuals. The licensee's radiation safety officer estimated the highest exposure to be between 3000 and 5600 millirem. The remaining overexposures, involving approximately ten other individuals, were estimated to be between 100 and 500 millirem total effective dose equivalent. The doses to the remaining members of the public were not expected to exceed 100 millirem total effective dose equivalent.

A patient who was administered a therapeutic quantity of sodium iodide iodine-131 on July 1, 2002, and hospitalized in accordance with 10 CFR Part 35.75, retained a significant portion of the administered dosage due to poor renal function, during her hospital stay. As such, radiation levels near the patient remained relatively high during this period. During the treatment period, hospital staff, including the former radiation safety officer (RSO), observed the patient's adult daughter frequently at the patient's bedside. Licensee staff, including the former RSO, did not take prudent precautions to maintain the daughter's dose as low as is reasonably achievable. The inspectors calculated the dose to the patient's daughter to be 15 rem total effective dose equivalent due to her proximity to the patient during her treatment, and the amount of time that she spent in areas of elevated radiation levels. The NRC's medical consultant, Dr. Edward Silberstein, determined that the exposure may result in less than a one percent increase in her lifetime risk of cancer.

After initially determining that public exposures likely exceeded regulatory limits, licensee staff, particularly the former RSO, were slow to investigate the circumstances associated with the overexposure. Licensee management did not initiate their investigation of the overexposures until July 26, 2002, 19 days after the event. The initial investigation was limited to interviews of hospital staff and a review of records of daily patient room surveys, and did not include interviews of the former RSO. The investigation was not conducted in a probing manner commensurate with the potential significance of the exposures.

The licensee's initial written report regarding exposures to members of the public in excess of the regulatory limit was limited to generalities regarding the radiological conditions pertinent to the exposures and the resultant doses to individuals. The report did not include the required information regarding doses to individuals, and included only a reference to exposure from a diagnostic radiology procedure, which was not in any units of dose (e.g., rem, rad, Gray, or Sievert). The licensee's October 1, 2002, follow-up report, provided nearly seven weeks after the initial report, required significant NRC staff involvement in order to obtain a specific dose estimate for any of the members of the public involved, and the technical bases for the estimate.

The inspectors identified three apparent violations of NRC regulatory requirements. The apparent violations included the failure to: (1) limit the dose to individual members of the public to 0.1 rem in a year; (2) use procedures and engineering controls, to the extent practical, based

upon sound radiation protection principles, to achieve doses to members of the public that are as low as is reasonably achievable; and (3) investigate an overexposure to a member of the public and implement corrective actions. In addition, the inspectors identified three potential violations of NRC regulatory requirements. The potential violations included the failure to: (1) include estimates of each individual's dose in the licensee's August 15, 2002, written report; (2) measure the dose rates in the contiguous unrestricted areas following the administration of a radiopharmaceutical therapy dosage requiring hospitalization; and (3) limit the dose in unrestricted areas to 2 millirem in any one hour.

The root cause of the apparent and potential violations was inattention to licensed responsibilities on the part of the former RSO. The former RSO stated that she had become distracted by other duties and responsibilities that affected her ability to focus on the regulatory and safety issues associated with the sodium iodide iodine-131 therapy procedure and the resultant public doses. Furthermore, the former RSO did not communicate her belief that public dose limits had been exceeded until the radiation safety committee meeting on July 17, 2002. After that meeting, licensee management did not investigate the exposures until after the former RSO's termination on July 26, 2002. This was not considered to be timely. The root cause of the potential violation associated with the August 15, 2002, report contents was unfamiliarity with NRC reporting requirements. The licensee's proposed corrective actions were adequate to address the potential violations. The adequacy of the licensee's corrective actions to address the apparent violations will be determined following the predecisional enforcement conference.

Report Details

1. Program Scope and Inspection History

License No. 21-00943-03 authorized St. Joseph Mercy Health System (licensee) to possess and use licensed materials for human medical purposes at the licensee's facilities located at St. Joseph Mercy Hospital, Ann Arbor, Michigan (hospital). The authorization included radiopharmaceuticals for diagnosis and therapy, and sealed sources for therapy.

The NRC last inspected the licensee on January 12, 2000, and identified one violation for failure to include all required information on written directives for radiopharmaceutical therapy. The NRC inspectors confirmed that the licensee's corrective actions for the violation have been adequate to prevent recurrence. This violation is closed. The licensee's failure to include all required information on the written directive did not result in any misadministrations or recordable events. During the previous inspection on February 11, 1997, the NRC identified one violation, involving the licensee's failure to secure from unauthorized access or removal, waste containing technetium-99m. This violation was closed during the January 12, 2000, inspection.

2. Sequence of Events

a. Inspection Scope

The inspection included a review of the sequence of events that resulted in exposures in excess of 100 millirem to several members of the public. The inspection also included tours of licensee facilities; interviews of selected licensee personnel; and reviews of the licensee's August 15, 2002, September 11, 2002, and October 1, 2002, written reports and other associated records.

b. Observations and Findings

On June 12, 2002, the licensee admitted a patient for treatment of metastatic thyroid carcinoma. During the treatment, a licensee authorized user physician prepared a written directive for the administration of 300 millicuries of sodium iodide iodine-131. The authorized user physician initially considered a dosage of 600 millicuries; however, due to the patient's poor renal function, he decreased the dosage to 300 millicuries.

On July 1, 2002, the licensee's former radiation safety officer (RSO) administered the radiopharmaceutical therapy dosage in accordance with the provisions of the written directive. The actual administered dosage was 285 millicuries. The patient remained hospitalized due to her other health problems and the patient control requirements in 10 CFR Part 35.75. The licensee provided the patient a private room with private sanitary facilities, posted the patient room door with the appropriate radiation warning signs, positioned shields at the foot of the bed and between the bed and door to the room, and provided radiation safety instructions to patient care staff, including instructions for the control of visitors. In addition, following administration of the therapy dosage, the RSO measured the radiation levels in the patient's room, the adjoining room, and the hallway outside the patient's room.

Typically, for patients with normal renal function, 90 to 95 percent of the administered dosage of sodium iodide iodine-131, which has not been taken up by the residual and metastatic thyroid tissues, is rapidly filtered from the blood stream (i.e., within 24 to 48 hours post-administration) via the kidneys and excreted in the urine. For such patients, there is a rapid reduction in the external radiation profile commensurate with the biological elimination of the unbound iodine-131. Following this initial rapid decline in external radiation levels, the levels would normally further diminish according to an effective half-life (due to a combination of physical radiological decay and biological elimination) of seven days.

During each day that the patient was hospitalized, the RSO measured radiation levels at the patient's bedside and at one meter from the patient. Due to the patient's poor renal function, typical biological elimination of the iodine-131 did not occur, and there was no initial rapid reduction in radiation levels. Radiation levels measured on July 1, 2002, post-administration of the therapy dosage, were 400 millirem per hour at the bedside and 40 millirem per hour at one meter. Radiation levels measured on subsequent days diminished according to an effective half-life of three to four days.

On July 1, 2002, all of the patient's visitors adhered to the radiation safety precautions instituted by the licensee. The primary precaution taken by the licensee was to not allow any visitors inside the patient's room during the first day after administration of the therapy dosage. This was confirmed through interviews of patient care staff and the patient's daughter. In keeping with its usual practice, the licensee relaxed visitor restrictions 24 hours after the administration of the dosage, and allowed visitors in the room. Hospital staff instructed the visitors to remain behind the shields during visitation; however, the licensee did not impose any stay time restrictions on the visitors.

Between July 2 and 7, 2002, several patient care staff and the RSO observed the patient's adult daughter frequently at the patient's bedside, near the window, where a shield was not located. When they observed this, they reminded the daughter to position herself on the other side of the bed so that she was protected from unnecessary radiation exposure. On July 5, 2002, the patient's physical condition worsened. The RSO and the authorized user physician approved the temporary removal of the bedside shields so that the patient's family members (estimates provided by hospital staff and the daughter vary between 20 and 35 individuals) could visit with the patient for the last time. Based on observations of the patient's room, the inspectors estimated that 10 - 12 individuals could have stood in close proximity to the bed, and received a dose of approximately 200 millirem total effective dose equivalent. Doses to all other family members in the patient's room would not likely have exceeded 100 millirem total effective dose equivalent.

The patient's condition declined until she died on July 7, 2002. Licensee patient care staff and the RSO observed the daughter at the bedside essentially continuously between July 5 and 7, 2002. The former RSO did not recommend further precautions to the daughter to maintain her radiation exposure as low as is reasonably achievable. Suggested precautions could have included maintaining an arm's length from the side of the patient's bed (since radiation levels at one meter were approximately one-tenth of those at the bedside), the use of additional shielding, minimizing the daughter's time at the bedside, or the use of a digital dosimeter to self-monitor the daughter's exposure, which the licensee had available. Part 20.1101(b) to Title 10 of the Code of Federal Regulations (10 CFR) requires that the licensee use, to the extent practical, procedures

and engineering controls, based upon sound radiation protection principles, to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable. The licensee's failure to use procedures and engineering controls, to the extent practical, based upon sound radiation protection principles, to achieve doses to members of the public that are as low as is reasonably achievable, is considered an apparent violation of 10 CFR Part 20.1101(b).

The former RSO stated that during the weekend of July 6 -7, 2002, she repeatedly attempted to contact her supervisor to relay her concern regarding potential exposures to members of the public. Interviews of the supervisor indicated that he had not received any pages or telephone calls to his residence. The supervisor stated that upon his return to work on July 8, 2002, he did not have any messages on his office telephone from the former RSO. Furthermore, he stated that the former RSO did not mention her concerns regarding public doses when she interacted with her supervisor following the patient's death.

Following the patient's death, the former RSO assisted a mortician during the embalming process. The embalming was performed in the hospital morgue. The former RSO provided the mortician with a digital dosimeter to monitor his exposure during the process. The dosimeter recorded an exposure of 35 millirem for the nine-hour procedure. Contaminated body fluids from the decedent were disposed to the sanitary sewer. Based on surveys conducted by the former RSO in the morgue and the patient's room, the licensee did not identify any significant residual contamination.

On July 17, 2002, the licensee's radiation safety committee convened for a regularly scheduled meeting. During the meeting, the committee members discussed the radiopharmaceutical therapy procedure that occurred on July 1 through 7, 2002, and the unique issues associated with it, including visitor control and the death of a patient during therapy. During those discussions, the former RSO indicated for the first time her belief that a member of the public received a dose in excess of 500 millirem, but she had not yet evaluated the extent of the exposure.

Parts 35.21(a) and (b) to 10 CFR require, in part, that the licensee appoint an RSO responsible for implementing the radiation safety program. The licensee, through the RSO, is required to ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program. The RSO is required to, among other things, investigate overexposures and deviations from approved radiation safety practices, and implement corrective actions as necessary.

The licensee's former RSO became aware that the daughter of a patient being treated with a radiopharmaceutical was not following the licensee's approved safety practices. In addition, the former RSO suspected that the patient's daughter had received an exposure to radiation in excess of the NRC's regulatory limits and failed to investigate the potential exposure and implement corrective actions. The former RSO's failure to investigate the potential overexposure and implement corrective actions is considered an apparent violation of 10 CFR Parts 35.21(a) and (b).

On July 26, 2002, the licensee terminated the former RSO's employment. Licensee management representatives stated that the termination was not related to the July 1 through 7, 2002, therapy treatment. At the time of her termination, the former RSO had

not yet evaluated the potential exposure to the patient's family members, including the patient's daughter.

c. Conclusions

A patient, who was administered a therapeutic quantity of sodium iodide iodine-131 on July 1, 2002, and hospitalized for compliance with 10 CFR Part 35.75, retained a significant portion of the administered dosage during her hospital stay. As such, radiation levels around the patient remained relatively high during this period. During the treatment period, hospital staff, including the licensee's former RSO, observed the patient's daughter frequently at the patient's bedside. Licensee staff, including the former RSO, did not take prudent precautions to maintain the daughter's dose as low as is reasonably achievable. Two apparent violations of regulatory requirements were identified, including the failure to: (1) use procedures and engineering controls, to the extent practical, based upon sound radiation protection principles, to achieve doses to members of the public that are as low as is reasonably achievable; and (2) investigate an overexposure to a member of the public and implement corrective actions as necessary.

3. Licensee Investigation

a. Inspection Scope

The inspection included a review of the results of the licensee's investigation of an event involving exposures in excess of 100 millirem to several members of the public. The inspection also included tours of facilities; interviews of selected licensee personnel; and a review of applicable procedures, associated records, and written reports.

b. Observations and Findings

Prior to the July 17, 2002, radiation safety committee meeting, the former RSO did not share with others her belief that a member of the public had received a radiation dose in excess of 500 millirem total effective dose equivalent. Before her termination on July 26, 2002, the former RSO had not evaluated the extent of the radiation exposure to the patient's daughter. The former RSO stated that she was focused on other activities, including shielding calculations for diagnostic radiology rooms and State registration of radiation producing devices (i.e., x-ray tubes).

Following termination of the former RSO, licensee management and the newly appointed RSO initiated an investigation into the exposures to members of the public associated with the July 1, 2002, administration of a radiopharmaceutical therapy dosage to a hospitalized patient. The investigation included a review of the records of the results of daily surveys conducted in the patient's room by the former RSO, and interviews of licensee staff who provided care to the patient. Based on anecdotal information obtained from patient care staff, licensee management bounded the maximum exposure received by a member of the public to approximately 3 rem total effective dose equivalent, and equated this to the dose received during a computed tomography (CT) scan.

c. Conclusions

Licensee staff, particularly the former RSO, were slow to investigate the circumstances associated with overexposures to members of the public resulting from the radiopharmaceutical therapy procedure performed on July 1 through 7, 2002. Licensee management did not initiate the investigation until July 26, 2002, nineteen days after the event. The initial investigation was limited to interviews of hospital staff and a review of records of daily patient room surveys, and did not include interviews of the former RSO or members of the patient's family. The investigation was not conducted in a probing manner commensurate with the potential significance of the exposures.

4. Notifications and Reporting

a. Inspection Scope

The inspection included a review of the notifications and reporting to the NRC of an event involving exposures to members of the public which resulted in doses in excess of 100 millirem in a year. The inspection also included interviews of selected licensee employees and a review of associated records and reports.

b. Observations and Findings

Title 10 CFR Part 20.2203(a) requires that each licensee submit a written report within 30 days of becoming aware that an individual member of the public received a dose in excess of the limits in 10 CFR Part 20.1301. Licensee staff initially determined that a member of the public likely received a dose in excess of 100 millirem total effective dose equivalent during the July 17, 2002, radiation safety committee meeting. Licensee staff provided a written notification to the NRC of this event in a letter dated August 15, 2002.

Title 10 CFR Part 20.2203(b) requires that each report required by 10 CFR Part 20.2203(a) describe the extent of exposure of individuals to radiation, including estimates of each individual's dose. The licensee's August 15, 2002, written report described the general radiological conditions in the patient's room, but did not provide specific dose estimates for any of the visitors. Licensee staff stated that the maximum likely dose to the visitors was the same as the dose expected from a CT scan, namely, 3 rem total effective dose equivalent. The licensee's failure to include estimates of each individual's dose in its August 15, 2002, written report is considered a potential violation of 10 CFR Part 20.2203(b).

On August 27, 2002, an NRC inspector contacted the licensee's current RSO to discuss the August 15, 2002, written report and obtain additional information. Since this individual had not been in the RSO position during the time that the event occurred, he was not familiar with any of the event details. The RSO indicated that he would need additional time to obtain the requested information.

On September 11, 2002, the RSO provided a follow-up written report regarding the public exposure event. The report included additional event details; however, the estimate for the maximally exposed individual was "... less than or equal to 3000 (millirem)." In addition, the RSO continued to rely on anecdotal information from patient care staff in developing the dose estimate. The inspector again requested that the RSO re-evaluate the dose estimate, and suggested that he use more definitive information regarding the duration of exposure and proximity of the daughter to the patient.

On October 1, 2002, the RSO submitted a third written report containing the detailed information requested by the inspector. In the subject report, the RSO revised his dose estimate for the patient's daughter to between 3000 and 5600 millirem total effective dose equivalent. The report provided the technical basis for the exposure estimate, including the results of interviews with the daughter.

c. Conclusions

The licensee's initial written report regarding exposures to members of the public in excess of the regulatory limit was limited to generalities regarding the radiological conditions pertinent to the exposures and the resultant doses to individuals. The report did not include the required information regarding doses to individuals, and included only a reference to exposure from a diagnostic radiology procedure, which was not in any units of dose (e.g., rem, rad, Gray, or Sievert). The licensee's October 1, 2002, follow-up report, provided nearly seven weeks after the initial report, required significant NRC staff involvement in order to obtain a specific dose estimate for any of the members of the public involved, and the technical bases for the estimate. One potential violation of regulatory requirements was identified involving the failure to include estimates of each individual's dose in the licensee's August 15, 2002, written report.

5. Public Dose Assessments

a. Inspection Scope

The inspection included a review of the licensee's assessments of doses to members of the public resulting from the July 1, 2002, radiopharmaceutical therapy dosage administration. The inspection also included interviews of selected licensee employees and the therapy patient's daughter, observations of facilities, and a review of associated records and reports.

b. Observations and Findings

Title 10 CFR Part 20.1301(a)(1) requires that the licensee conduct operations so that the total effective dose equivalent to individual members of the public from the licensed operations does not exceed 0.1 rem (100 millirem) in a year. The licensee estimated the daughter's dose to be 3 to 5.6 rem (3000 to 5600 millirem) total effective dose equivalent. The estimate was based on information provided by the daughter regarding her activities between July 5 and 7, 2002. The RSO, who performed the dose estimate, was not aware that the daughter had been near the patient's bedside periodically between July 2 through 5, 2002.

During the inspectors' interviews of the patient's daughter, she provided the following information regarding her proximity to the patient and duration of exposure:

- On July 1, 2002, following administration of the therapy dosage, all family members remained at the doorway to the patient's room during visitation, as instructed by hospital staff.

- Beginning approximately mid-day on July 2, 2002, through the late afternoon of July 5, 2002, the daughter remained at the patient's bedside approximately half of each day.

- Beginning at approximately 5 p.m. on July 5, 2002, after the patient's condition worsened, the daughter remained at the bedside continuously, except for approximately 3.5 hours, until the patient's death on July 7, 2002.

- When at the patient's bedside, the daughter sat against the bed, with her elbows or forearms on the bed.

- No other family members remained in the patient's room for as long, or positioned themselves as close, as the daughter did.

Based on bedside radiation level surveys performed by the former RSO, and the information provided by the patient's daughter, the inspectors calculated the daughter's dose at 15 rem total effective dose equivalent, as follows:

July 2, 2002: 6 hours @ 348 millirem per hour

July 3, 2002: 12 hours @ 250 millirem per hour

July 4, 2002: 12 hours @ 210 millirem per hour

July 5, 2002 (through 5 p.m.): 8.5 hours @ 210 millirem per hour

July 5, 2002 (after 5 p.m.): 7 hours @ 210 millirem per hour

July 6, 2002: 20.5 hours @ 132 millirem per hour

July 7, 2002: 11.5 hours @ 107 millirem per hour

The main difference between the licensee's estimate of the daughter's dose as provided in the October 1, 2002, written report, and the inspectors' estimate was additional detail provided by the daughter during the inspectors' interview on October 4, 2002. The additional detail concerned the daughter's bedside proximity during July 2, 2002 through July 5, 2002, which she had not recalled during earlier conversations with licensee staff. The licensee's failure to limit the dose to individual members of the public from licensed operations to 0.1 rem in a year is considered an apparent violation of 10 CFR Part 20.1301(a)(1). At the time of the inspection, the licensee did not dispute the inspectors' estimate of the daughter's exposure, but the RSO stated that he would need additional time to review the inspectors' assumptions and the outcomes of their calculations.

The former RSO did not measure the radiation levels in an emergency exit stairwell next to the patient's room and along the wall where the head of the patient's bed was located; however, all entry points to the stairwell were via alarmed fire/emergency exit doors. In addition, the former RSO did not survey the area outside the window of the patient's room, which was on the ground floor. The former RSO did not place any shields between the patient's bed and the window. The stairwell and the area outside the patient's window were not restricted for purposes of radiation protection. Title 10 CFR Part 35.315(a)(4) requires that the licensee promptly measure the dose rate in contiguous restricted and unrestricted areas, with a radiation measurement survey instrument, to demonstrate compliance with the requirements of 10 CFR Part 20, after administration of a radiopharmaceutical therapy dosage requiring hospitalization in

order to comply with 10 CFR Part 35.75. The licensee's failure to measure the dose rates in the contiguous unrestricted areas, located in the stairwell and outside the window, following the administration of a radiopharmaceutical therapy dosage requiring hospitalization to comply with 10 CFR Part 35.75 is considered a potential violation of 10 CFR Part 35.315(a)(4).

Title 10 CFR Part 20.1301(a)(2) requires that the licensee conduct operations so that the dose in any unrestricted area from external sources does not exceed 2 millirem in any one hour. The inspectors requested that the licensee evaluate the likely radiation levels in the unrestricted areas that were not surveyed following the administration of the radiopharmaceutical therapy dosage on July 1, 2002. The current RSO determined, based on surveys performed in the patient's room, that the radiation levels in the stairwell adjacent to the room ranged from 10 millirem in an hour on July 1, 2002, to 4 millirem in an hour on July 7, 2002. The current RSO also determined that outside the patient's window, the radiation levels ranged from 17 millirem in an hour on July 1, 2002, to 8 millirem in an hour on July 7, 2002. The licensee's failure to limit the dose in unrestricted areas from licensed operations to 2 millirem in any one hour during the period from July 1 through 7, 2002, is considered a potential violation of 10 CFR Part 20.1301(a)(2).

c. Conclusions

Based on additional information obtained during the inspection, the inspectors calculated the dose to the patient's daughter to be 15 rem total effective dose equivalent, due to her proximity to the patient during the patient's treatment, and due to the amount of time that she spent in areas of elevated radiation levels. At the time of the inspection, licensee staff were not able to re-evaluate their earlier dose estimates based on the recency of the additional information. In addition, the inspectors identified that elevated radiation levels existed in two unrestricted areas during the patient's radiopharmaceutical therapy treatment. However, due to the nature of the areas, exposure to members of the public was not likely. One apparent violation of regulatory requirements was identified for failing to limit the dose to individual members of the public to 0.1 rem in a year. In addition, two potential violations of regulatory requirements were identified, including the failures to: (1) limit the dose in unrestricted areas to 2 millirem in any one hour, and (2) measure the dose rates in the contiguous unrestricted areas following the administration of a radiopharmaceutical therapy dosage requiring hospitalization.

6. Quality Management Program Implementation

a. Inspection Scope

The inspection included a review of the licensee's implementation of its written quality management program procedures which consisted of interviews of selected licensee personnel and reviews of applicable procedures and associated records.

b. Observations and Findings

The written directive for the July 1, 2002, administration of a therapeutic quantity of sodium iodide iodine-131 included a prescribed dosage of 300 millicuries. The administered dosage was 285 millicuries. The written directive was signed and dated by an authorized user physician and included all of the information specified in 10 CFR Part 35.2. Licensee staff verified the dosage in a dose calibrator prior to administration, and confirmed that the dosage was within ten percent of the prescribed dosage.

The inspectors reviewed selected administrations of therapeutic radiopharmaceuticals. The administrations reviewed included nine signed and dated written directives completed prior to July 1, 2002. In each case, licensee staff verified the dosage in a dose calibrator and the identity of the patient prior to administering the dosage. The former RSO audited all administrations of therapeutic quantities of radiopharmaceuticals at least once each year to ensure that the administrations were in accordance with the associated written directive. The former RSO had not identified any recordable events or misadministrations as a result of previous audits.

c. Conclusions

The licensee adequately implemented the written procedures of its quality management program for therapeutic radiopharmaceutical administrations. The inspectors did not identify any problems with regard to those administrations in general, or specifically with regard to the July 1, 2002 administration, which was the subject of this inspection.

7. Licensee Corrective Actions

a. Inspection Scope

The inspection included a review of the licensee's proposed corrective actions for the event involving exposures in excess of 100 millirem to several members of the public. The review included interviews of selected licensee personnel.

b. Observations and Findings

The licensee provided its initial corrective actions in its August 15, 2002, written report of the event involving several public exposures in excess of the regulatory limit. The actions were limited to documenting agreement between the authorized user and anyone visiting patients that have been hospitalized for compliance with 10 CFR Part 35.75, that the visitors will comply with the controls established by the licensee. The licensee also committed to enhancing documentation of visitor stay times within the rooms of patients hospitalized for compliance with 10 CFR Part 35.75, providing larger radiation warning signs for the patient's room door, and making individual education sheets available to visitors.

During the inspection, the licensee provided additional corrective actions in an October 8, 2002 letter. The additional actions included establishing a policy of not allowing visitors into hospitalized therapy (radiopharmaceutical and sealed source) patient rooms. In those instances when an authorized user deems it appropriate for visitors to enter such patient rooms, the licensee will provide more formalized instruction to the visitors regarding visitation restrictions; use available resources to develop a

balanced solution that meets the needs of patients and their families, while fulfilling regulatory responsibilities; and ensure that management is promptly notified of any concerns regarding patient or visitor compliance with radiation safety restrictions or precautions.

c. Conclusions

The licensee's proposed corrective actions were adequate to address the problems associated with the exposures to members of the public arising from the July 1 through 7, 2002 radiopharmaceutical therapy procedure.

8. NRC Medical Consultant's Review

The NRC staff contracted with a medical consultant, Edward Silberstein, M.D., to review the possible health effects associated with the dose to the patient's daughter as a result of this event. Dr. Silberstein opined that the exposure to the patient's daughter may result in less than a one percent increase in her lifetime risk of cancer.

9. Exit Meeting

On October 5, 2002, the inspectors summarized the initial findings at a preliminary exit meeting with licensee representatives. The summary included the inspectors' understanding of the sequence of events, the preliminary dose assessment for the patient's daughter, and the licensee's proposed corrective actions. On October 16, 2002, the Chief, Materials Inspection Branch, and the inspectors summarized the inspection findings at a second preliminary exit meeting with licensee representatives. The summary reiterated the findings from the first preliminary exit meeting, included the identified apparent violations, and described the NRC's process for use of a medical consultant. The final exit meeting was conducted by telephone on November 21, 2002, to discuss the apparent violations. The licensee did not identify any material reviewed during the inspection and proposed for inclusion in this report as proprietary in nature.

PARTIAL LIST OF PERSONS CONTACTED

Elizabeth Beger, R.N., Service Delivery Leader, 1000 Oncology Unit
Rayma Bilicki, M.S., Radiation Safety Officer (through July 26, 2002)
Sharlene Campbell, Director, Radiology
John E. Freitas, M.D., Authorized User Physician
Amy S. Harrison, M.S., Medical Physicist
Michelle Hazard, Manager, Radiation Oncology and Radiation Safety
Timothy G. Kensora, M.S., Radiation Oncology Physicist, and
Radiation Safety Officer (after July 26, 2002)
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Chief Operating Officer
Mandi A. Murray, Assistant General Counsel
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patient's daughter* - name withheld to protect personal privacy